

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): A method of sterilizing a balloon susceptible to degradation by ionizing radiation, comprising

(a) packaging said balloon in a pouch capable of providing a barrier to atmospheric oxygen, wherein said pouch includes a first layer including a plastics-coated foil, a porous second layer, and a third layer including a plastics-coated foil, wherein said second layer is between the first and third layers;

(b) exposing said balloon enclosed in said pouch to a nitrogen gas flush sufficient to reduce the oxygen content within said pouch to less than about 10%; and

(c) exposing said balloon enclosed in said pouch to ionizing radiation, wherein said ionizing radiation is either gamma radiation or electron beam radiation at a dose of no greater than about 100 kGy.

Claim 2 (original): A method according to claim 1, wherein said balloon is part of a balloon dilatation catheter.

Claim 3 (original): A method according to claims 1 or 2, wherein said balloon is manufactured from one or more block polymers selected from the group consisting of polyester block copolymers, polyamide block copolymers, polyurethane block copolymers, a mixture of nylon and polyamide block copolymers, and a mixture of polyethylene terephthalate and polyester block copolymers.

Claim 4 (cancelled).

Claim 5 (currently amended): A method according to claim [[4]] 1, wherein said pouch comprises:(a)—a first layer comprising comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ Clear EZ PEEL® Peel® material; (b)—a said second layer comprising comprises 2FS Uncoated TYVEK® Tyvek® material, having a porosity of 18-240 seconds by the Gurley porosimeter test[[;]] and (c)—a said third layer comprising comprises 12 μ PET, 25.4 μ

WPE/Foil/Adhesive and 50 μ Clear EZ PEEL® Peel® material; wherein said second layer is between said first and third layers.

Claim 6 (original): A method of claims 1 or 2, wherein said pouch further comprises an oxygen absorber.

Claim 7 (original): A method according to claim 1, wherein said oxygen content is between about 5% and about 10%.

Claim 8 (original): A method according to claim 1, wherein said oxygen content is less than about 1%.

Claim 9 (original): A sterilized balloon prepared by a method according to claim 1.

Claim 10 (original): A sterilized balloon catheter prepared by the method according to claim 2.

Claim 11 (currently amended): A method of sterilizing a balloon susceptible to degradation by ionizing radiation, comprising:

(a) packaging said balloon in a pouch capable of providing a barrier to atmospheric oxygen, wherein said pouch includes a first layer including a plastics-coated foil, a porous second layer, and a third layer including a plastics-coated foil, wherein said second layer is between the first and third layers;

(b) exposing said balloon enclosed in said pouch to a nitrogen gas flush sufficient to reduce the oxygen content in said pouch; and

(c) exposing said balloon enclosed in said pouch to ionizing radiation, while avoiding the concomitant degradation associated with sterilization at atmospheric oxygen levels.

Claim 12 (original): A method according to claim 11, wherein said balloon is part of a balloon dilatation catheter.

Claim 13 (original): A method according to claims 11 or 12, wherein said balloon is manufactured from one or more block polymers selected from the group consisting of

polyester block copolymers, polyamide block copolymers, polyurethane block copolymers, a mixture of nylon and polyamide block copolymers, and a mixture of polyethylene terephthalate and polyester block copolymers.

Claim 14 (canceled).

Claim 15 (currently amended): A method according to claim [[14]] 11, wherein said pouch comprises:(a) —— a first layer comprising comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ Clear EZ PEEL® Peel® material; (b) —— a said second layer comprising comprises 2FS Uncoated TYVEK® Tyvek® material, having a porosity of 18-240 seconds by the Gurley porosimeter test[[;]] and (c)—a said third layer comprising comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ Clear EZ PEEL® Peel® material; wherein said second layer is between said first and third layers.

Claim 16 (original): A method of claims 11 or 12, wherein said pouch further comprises an oxygen absorber.

Claim 17 (original): A method according to claim 11, wherein said ionizing radiation is either gamma irradiation or electron beam irradiation.

Claim 18 (original): A method according to claim 17, wherein said gamma irradiation is administered at a dose rate of about 1 kGy/hrs to about 10 kGy/hrs.

Claim 19 (original): A method according to claim 17, wherein said electron beam irradiation is administered at a dose rate of no greater than about 20 kGy/s.

Claim 20 (original): A method according to claim 11, wherein said nitrogen gas flush is administered at a pressure of less than about 10 psi and said oxygen content is less than about 10%.

Claim 21 (original): A method according to claim 20, wherein said oxygen content is between about 5% and about 10%.

Claim 22 (original): A method according to claim 20, wherein said oxygen content is less than about 1%.

Claim 23 (original): A sterilized balloon prepared by a method according to claim 11.

Claim 24 (original): A sterilized balloon catheter prepared by the method according to claim 12.